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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/557,286	08/24/2007	Benedict Marie Doorschodt	0470-053534	8521

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EXAMINER

SZMAL, BRIAN SCOTT

ART UNIT	PAPER NUMBER
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3736

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03/13/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/557,286	Applicant(s) DOORSCHODT, BENEDICT MARIE	
	Examiner Brian Szmal	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 December 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-25 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 19 is/are allowed.
- 6) ☒ Claim(s) 13-18, 20 and 22-25 is/are rejected.
- 7) ☒ Claim(s) 21 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 December 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>12/3/08</u> . | 6) <input type="checkbox"/> Other: _____ |

Information Disclosure Statement

1. The information disclosure statement filed December 3, 2008 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered.

The cited Chinese document does not have an English abstract, nor is there any explanation of what the reference discloses. The IDS statement discloses an English abstract has been provided, but no such abstract has been submitted.

Claim Objections

2. Claim 13 is objected to because of the following informalities: In line 5, it is unclear to the Examiner what "itself" refers to in the claim. Appropriate correction is required.

3. Claim 19 is objected to because of the following informalities: In line 5, it is unclear to the Examiner what "itself" refers to in the claim. Appropriate correction is required.

4. Claim 21 is objected to because of the following informalities: In line 2, "locations" should read as "points" since Claim 18 discloses the use of "points". Appropriate correction is required.

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5. Claim 22 is objected to because of the following informalities: In line 3, it is unclear to the Examiner what "it" refers to in the claim. Appropriate correction is required.

6. Claim 25 is objected to because of the following informalities: The claim utilizes the phrase "in its entirety". The phrase should be deleted from the claim because the phrase is not required in the context of the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 13, 14, 17, 24 and 25 are rejected under 35 U.S.C. 102(e) as being anticipated by Garcia (2003/0097079 A1).

Garcia discloses a biopsy needle sheath and further discloses an insertion instrument and a sleeve of bioabsorbable material defining an interior for guiding the instrument; the sleeve having an opening and comprising a stop adjacent the opening (the stop can be seen in at least Figures 1 and 3, wherein the stop is located at the proximal end of the sleeve, preventing the instrument being placed inside the sleeve from traveling farther than the proximal end of the sleeve), the sleeve being made of a

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material that is relatively rigid outside the body and becomes softer after the introduction into the body and collapses onto itself when the instrument is withdrawn; the sleeve is made of a material that is relatively rigid below 30°C and not in contact with water and is relatively soft at temperatures between 35-40°C and in contact with moisture; and the sleeve has blood staunching properties on the outside. See Paragraphs 0032, 0060, 0067, 0076, 0080, 0083, 0085, 0089 and 0094.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garcia (2003/0097079 A1) as applied to claim 13 above, and further in view of Barrows (6,884,427 B1).

Garcia, as discussed above, discloses a bioabsorbable sheath but fails to disclose the type of material; and the material is a combination of polyglycolide, polylactic acid and caprolactone in certain percentages.

Barrows discloses a means for introducing agents into the body and further discloses the type of material; and the material is a combination of polyglycolide, polylactic acid and caprolactone in certain percentages. See Column 6, lines 42-53.

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Garcia to include the specific composition of the bioabsorbable sheath, as per the teachings of Barrows, since it is well known in the art to utilize such compounds as polylactic acid, polyglycolide and caprolactone in a bioabsorbable device. Furthermore, it would have been obvious to one of ordinary skill in the art to obtain the specific percentages of the compounds in a combination through routine experimentation.

11. Claims 18, 20, 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garcia (2003/0097079 A1) as applied to claim 13 above, and further in view of Haaga (4,838,280).

Garcia, as discussed above, discloses a bioabsorbable sheath, and further discloses the sheath is designed for direct contact with the insertion instrument and the body; the sleeve comprises a continuous base sleeve of flexible material and a number of rings arranged around it; and the sleeve has a thickness of 0.1-1.5mm.

Garcia however fails to disclose the sleeve has break points at a distance from the distal end of the sleeve.

Haaga discloses a hemostatic sheath and further discloses the sleeve has break points at a distance from the distal end of the sleeve. See Column 11, lines 14-20.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Garcia to include the use of at least one break point, as per the teachings of Haaga, since it would provide a means of separating the hemostatic sleeve from the device during withdrawal from the body.

Allowable Subject Matter

12. Claim 21 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

13. The following is a statement of reasons for the indication of allowable subject matter: Claim 19 remains allowable per the reasons set forth in the Office Action mailed on June 3, 2008.

Response to Arguments

14. Applicant's arguments, filed December 3, 2008, with respect to the rejection of Claims 14, 18, 21, 23 and 24 under 35 USC 112 have been fully considered and are persuasive. The rejection of Claims 14, 18, 21, 23 and 24 has been withdrawn.

15. Applicant's arguments filed December 3, 2008 have been fully considered but they are not persuasive.

16. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the sleeve extends from the target organ, through intervening tissues and organs and subsequently through the skin of the body) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

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17. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the stop abuts against the skin of the patient, preventing skin contamination) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Conclusion

18. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmaj whose telephone number is (571)272-4733. The examiner can normally be reached on Monday-Friday, with second Fridays off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian Szmal/
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736